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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,874	11/21/2001	Wing L. Sung	07121.0003U1	2196

23859 7590 12/21/2006

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EXAMINER	
RAO, MANJUNATH N	
ART UNIT	PAPER NUMBER
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/990,874	SUNG, WING L.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7,9,11-14,16,18,20-23,25,27,29-32,34,37-41,43,44,46,48,49 and 56-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence alignments*.

DETAILED ACTION

Claims 1-2, 4-7, 9, 11-14, 16, 18, 20-23, 25, 27, 29-32, 34, 37-41, 43-44, 46, 48-49, 56-71 are still at issue and are present for examination.

Applicants' amendments and arguments filed on 8-11-06, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Specifically, Examiner has withdrawn the rejection of claims 1-2, 4-7, 9-16, 18-25, 27-34, 37-46, 48, 56-71 are rejected under 35 U.S.C. 102(e) as being anticipated by NRC of Canada (NRC) et al. (WO 01/92487 A2, Dec 6, 2001, filed in English, designating US, filed on 5-31-2001 with priority benefit to US 60/213,803, 5-31-2000) or Wing Sung (US20030166236 A1, published 9-4-03, with priority date 5-31-2001) in view of the persuasive arguments. However, said rejections have been modified and new ones added in view of the applicant's explanation on the nature of the variant claimed, i.e., any xylanase variant comprising the (amended) modified amino acids at the indicated positions and not limited to variants of SEQ ID NO:16 comprising said changes and that it is the positions of the amino acid substitutions which are determined by alignment with the amino acid sequence of SEQ ID NO:16. Examiner thanks applicants for clarifying this issue as well as for providing a summary of the claimed subject matter in other applications by the inventor.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-7, 9, 11-14, 16, 18, 20-23, 25, 27, 29-32, 34, 37-41, 43-44, 46, 48-49, 56-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific variants of xylanase with SEQ ID NO:16 comprising a substitution at one or more positions as follows, a non-polar amino acid at position 116, a Cys at position 118, a basic amino acid at positions 144 and 161 of SEQ ID NO:16, followed by modification of said variants comprising other changes at positions wherein said positions are limited to positions 10, 11, 27, 29, 75, 105, 125, 129, of SEQ ID NO:16, such that the modified xylanase continues to be classified in "Family 11" and continues to have thermophilic xylanase activity and a method of using said variant xylanase (claim 48) in pulp manufacturing, does not reasonably provide enablement for any modified xylanase comprising simply a non-polar amino acid at position 116, a Cys at position 118, a basic amino acid at positions 144 and 161 wherein said positions correspond to the amino acid positions in SEQ ID NO:16. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-2, 4-7, 9, 11-14, 16, 18, 20-23, 25, 27, 29-32, 34, 37-41, 43-44, 46, 48-49, 56-71 are so broad as to encompass any modified xylanase comprising a change in any amino acid

position in SEQ ID NO:16 with the proviso that said variant comprises primarily one or more amino acid positions selected from the group 116, 118, 144 and 161, where the amino acid at position 116 is a polar amino acid, a Cys at position 118 and a basic amino acid at positions 144 and 161 when aligned with SEQ ID NO:16. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of xylanases broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to a modified xylanase of SEQ ID NO:16 comprising specific substitutions at positions 10, 11, 27, 29, 75, 105, 116, 118, 125, 129, 144, 161 with specific amino acids. It would require undue experimentation of the skilled artisan to make and use all of the claimed polypeptides. The specification is limited to teaching the use of SEQ ID NO:16 as parent xylanase wherein amino acids at specific positions such as 10, 11, 27, 29, 75, 105, 116, 118, 125, 129, 144, 161 can be substituted with other specific amino acids but provides no guidance with regard to the making of any or all variants and mutants or with regard to other uses comprising modifying any or all amino acids in SEQ ID NO:16. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary

Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any xylanase or SEQ ID NO:16 because the specification does not establish: (A) regions of the protein structure which may be modified without affecting xylanase activity; (B) the general tolerance of xylanases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue in the sequence with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including xylanases with an enormous number of amino acid modifications

or modification of SEQ ID NO: 16. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of xylanase variants having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the previous office action, applicants have argued at length traversing the above rejection. Basically, applicants argue that the modified xylanase of claim 1 and 49 is a Family 11 xylanase and exhibits improved thermophilicity and that sufficient guidance is provided in the specification as to which amino acids of family 11 xylanases would be potentially tolerant of modification and that amino acid sequences of numerous family 11 xylanases are known in the art. Applicants also argue that information such as the conserved amino acids and non-conserved amino acids are provided in the specification and a person of skill in the art can carry out an experiment to determine if the xylanase is more active at higher temperature. Examiner respectfully disagrees with such an argument as being persuasive to overcome the rejection. This is because contrary to applicant's argument the claims are not simply limited to variants of SEQ ID NO:16 wherein said variants comprise changes only a those positions indicated. Claims are drawn to any variant having any amino acid sequence with the proviso that when aligned with SEQ ID NO:16, said variant has the specific amino acids claimed at specific positions. The specification lack guidance as to how one of ordinary skill in the art would make all the variants claimed wherein all the amino acids are modified. Contrary to applicant's argument even though the specification may teach what is a conserved amino acid

and what is not, the claims are not limited to variants that have modifications only in the non-conserved amino acids. Claims are drawn to any or all variants comprising any amino acids with the proviso that they have the specific amino acid modifications when aligned with SEQ ID NO:16.

Applicants argue that claims need not be limited to specific exemplified embodiments or technical examples disclosed in the specification and that it is only necessary that one of skill in the art be able to practice the invention given the knowledge and skill in the art. Applicants argue that example 1 in the specification describes the construction of various modified xylanases and this is sufficient disclosure to satisfy the enablement requirement. With the guidance provided in the specification it would not require undue experimentation to produce the claimed variant. Examiner respectfully disagrees with all the above arguments and asserts that claims continue to suffer from enablement issues. This is because, irrespective of whatever guidance is provided in the specification or in the art, one of ordinary skill in the art will be subject to undue experimentation in order to arrive at active polypeptides having thermophilic xylanase activity as claimed. Although the claims are not limited to variants having only a single amino acid substitution, in order to generate only *single* amino acid variants of SEQ ID NO:16, one must make 19^{190} just for *single amino acid variants*. This number was determined by recognizing that SEQ ID NO:16 is 190 amino acids in length. Because there are 19 other possible naturally occurring L-amino acids that can replace any one amino acid of SEQ ID NO:16, the number of possible variations is 19^n, where n = number of amino acids in a polypeptide. Thus, for only *single* amino acid substitutions, the number of variants is 19^{190} and the number becomes seemingly infinite when one considers that the claims broadly encompass

simultaneous alteration of substitution, addition, deletion, and/or insertion of all 190 amino acids. Based on this rough approximation, *the number of allowed permutations is astounding.* While methods to produce variants of a known sequence, e.g., site-specific mutagenesis and random mutagenesis, are well-known to the skilled artisan, producing variants having increased thermophilic xylanase activity as claimed requires that one of skill in the art know or be provided at least with guidance for making and selecting which of the *at least* 19^{190} variants has the desired activity. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the at least 19^{190} possible variants. Current techniques (i.e., high throughput mutagenesis and screening techniques) in the art would allow for finding a few active mutants within several hundred thousand or up to about a million inactive mutants but finding a few mutants within several billion or more as claimed would not be possible. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has **not** been provided in the instant specification.

Next applicants also argue that if the claims scope is narrowed as suggested by Examiner to that of SEQ ID NO:16, then one of skill in the art upon reading the present specification, may identify one or more analogous positions within a family 11 xylanase listed in Figure 1, or any other family 11 xylanase, and modify these positions using standard techniques to circumvent the claim and in doing so, the person of skill would not have exercised any inventive ingenuity, yet relied upon the teaching of the specification to arrive at the teaching of the present invention. Examiner respectfully disagrees with such an argument

as being persuasive to overcome the above rejection. Applicants have several ways to overcome such problems and Examiner suggests exploring them.

Claims 1-2, 4-7, 9, 11-14, 16, 18, 20-23, 25, 27, 29-32, 34, 37-41, 43-44, 46, 48-49, 56-71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-2, 4-7, 9, 11-14, 16, 18, 20-23, 25, 27, 29-32, 34, 37-41, 43-44, 46, 48-49, 56-71 are directed to any or all variants of SEQ ID NO:16 wherein any amino acid position is modified by at least one of deletion, addition, insertion and substitution with any other amino acid with the provision that said variants also comprises specific substitutions at one or more positions from the group consisting of positions 10, 11, 27, 29, 75, 105, 116, 118, 125, 129, 144, 161 when aligned with SEQ ID NO:16. Above claims are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides derived from SEQ ID NO:16 including modified polypeptide sequences comprising specific substitutions at positions 10, 11, 27, 29, 75, 105, 116, 118, 125, 129, 144, 161, and other modifications that have not been disclosed in the specification. No description has been provided of all the modified polypeptide sequences encompassed by the claim. No information, beyond the characterization of SEQ ID NO:16 and the specific positions 10, 11, 27, 29, 75, 105, 116, 118, 125, 129, 144, 161 that can be substituted with other specific amino acids has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The

specification does not contain any disclosure of the structure of all the polypeptide sequences derived from SEQ ID NO:16, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of structures. Therefore many structurally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In response to the previous Office action, applicants traverse the above rejection arguing that possession of an invention is not limited to a description of actual reduction to practice and possession of a claimed invention may be shown by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Applicants argue that the specificity of disclosure necessary to satisfy the written description requirement depends on the level of skill and knowledge in the art and in the present case, the amino acid sequences of numerous Family 11 xylanases are disclosed in Figure 1 and the sequence listing. Applicants maintain that from aligning the sequences one of skill in the art can determine that certain amino acids in the sequence are conserved. Equipped with the

amino acid sequences disclosed in Figure 1, it would be a simple matter for a person of skill in the art to produce a modified Family 11 xylanase comprising one or more of the substituted amino acids recited in claim 1 by employing well-known recombinant techniques such as plasmid preparation, restriction enzyme digestion, polymerase chain reaction, oligonucleotide phosphorylation, ligation, transformation and DNA hybridization (see page 26, lines 1-5). Applicants submit that the broad disclosure of the Family 11 amino acid sequences and which amino acids are conserved, coupled with the ease with which a person of skill in the art could prepare a modified xylanase, makes it clear that the invention is described with sufficient specificity to convey that the applicant invented the subject matter of claim 1. Examiner respectfully disagrees with such an argument. Contrary to applicant's argument, claims are not simply limited to those variants in which the conserved amino acids are retained and those not conserved are the only ones being modified. Furthermore, claims are not limited to few variants of family 11 xylanases and examiner has given little weight for the phrase "family 11". This is because, applicants have not specifically described the same in terms of structural features as to what defines a sequence as belonging to family 11 and what sequences define non-family 11 sequences. Furthermore, as explained in the enablement rejection claims are drawn to an enormous number of variants of SEQ ID NO:16 and others with the only proviso that they have the specific modifications at positions 116, 118, 144 and 161. Except for this description, there is no other structural description of all the variants encompassed in the claims. Applicants do argue that family 11 xylanases share extensive amino acid sequence similarity and share the same molecular structure. However, in terms of amino acid sequence, neither the applicants nor the art sets aside specific signatures of

family 11 xylanases. However, applicants fail to provide a representative structure of all the variants claimed. While applicants argue that representative disclosures of *T.reesei* xylanase II mutants is adequate, claims are not limited to such a specific mutant.

As discussed in the written description guidelines, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. **Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.** Satisfactory disclosure of a representative number depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. In the instant case the claimed genera of xylanases includes species which are widely variant in structure. The genus claimed is structurally diverse as it encompasses variant polypeptides of SEQ ID NO:16 but also of any polypeptide with xylanase activity. As such, neither the description of the structure and function of SEQ ID NO:16 nor the disclosure solely of functional features present in all members of the genus is sufficient to be

representative of the attributes and features of the entire genus. Hence the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 4, 9, 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Paloheimo et al. (US 6228629) or Van Ooigen et al. (US 5610046) or Hansen et al. (US 5817500). This rejection is based upon the public availability of patents granted to another. Claims 1-2, 4, 9 of the instant application are drawn to a modified xylanase comprising at least one or more than one substituted amino acid residue at a position selected from the group consisting of 1)a non-polar amino acid at position 116, 2)a Cys at position 118, 3)a basic amino

acid at positions 144 or 161, said positions determined from sequence alignment of said modified xylanase with *T.reesei* xylanase amino acid sequence defined in SEQ ID NO:16, wherein the modified xylanase exhibits improved characteristics corresponding to native xylanase and is used for an industrial process such as paper pulp manufacture.

Paloheimo et al. or Van Ooigen et al. disclose an identical xylanase which encompasses a variant comprising a substitution at positions 144, 161 with a basic amino acid, a Lysine, said position determined from sequence alignment of said modified xylanase with *T.reesei* xylanase amino acid sequence defined in SEQ ID NO:16, wherein the modified xylanase exhibits improved characteristics (see) and its use in a industrial process such as paper pulp manufacture. The references may not explicitly state that the thermophilicity of said modified xylanase was improved the native xylanase. However, because the reference xylanase comprises the very same mutation that is being claimed here, Examiner takes the position that said functional characteristic is an inherent characteristic of said modified xylanase. Thus Paloheimo et al. or Van Ooigen et al. anticipate claims 1-2, 4, 9, 48 of this application as written (see enclosed sequence alignments).

Claims 1-2, 4, 9, 18, 48, 56, 67 are rejected under 35 U.S.C. 102(e) as being anticipated by Hansen et al. (US 5817500). This rejection is based upon the public availability of patents granted to another. Claims 1-2, 4, 9, 18, 48, 56, 67 of the instant application are drawn to a modified xylanase comprising at least one or more than one substituted amino acid residue at a position selected from the group consisting of 1)a non-polar amino acid at position 116, 2)a Cys at position 118, 3)a basic amino acid at positions 144 or 161, and wherein said modified

xylanase further comprises an Asp at position 11, and the basic amino acid at position 144 or position 161 is Lys, Arg or both positions are Arg, said positions determined from sequence alignment of said modified xylanase with *T.reesei* xylanase amino acid sequence defined in SEQ ID NO:16, wherein the modified xylanase exhibits improved characteristics corresponding to native xylanase and is used for an industrial process such as paper pulp manufacture.

Hansen et al. disclose an identical xylanase which encompasses a variant comprising a substitution at positions 144, 161 with a basic amino acid, a Lysine and an Arg, an Asp in position 11, and Gly as the non-polar amino acid at position 118said position determined from sequence alignment of said modified xylanase with *T.reesei* xylanase amino acid sequence defined in SEQ ID NO:16, wherein the modified xylanase exhibits improved characteristics (see) and its use in a industrial process such as paper pulp manufacture. The references may not explicitly state that the thermophilicity of said modified xylanase was improved the native xylanase. However, because the reference xylanase comprises the very same mutation that is being claimed here, Examiner takes the position that said functional characteristic is an inherent characteristic of said modified xylanase. Thus Paloheimo et al. or Van Ooigen et al. anticipate claims 1-2, 4, 9, 18, 48, 56, 67 of this application as written.

Double Patenting

The provisional nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This is a provisional rejection since the application has not issued as a patent.

Claims 1, 2, 4, 9, 48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 4-6, 34-42 of U.S. application no.11/377644. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1, 2, 4, 9, 48 of the instant application and claims 1-2, 4-6, 34-42 of the reference patent are both directed to variants of xylanase having an amino acid sequence in which the amino acid at one or more positions 144 and 161 are substituted with another by aligning the sequence with SEQ ID NO:16, wherein said xylanase is from family 11 and from *Trichoderma reesei*. The only difference between the two set of claims is that the instant claims are drawn to a variant wherein the substituted amino acids at positions 144 and 161 are specifically a basic amino acid as opposed to no such limitation in the reference application. However, the reference application teaches in the specification that mutants may be constructed by substituting a basic amino acid at position 144 or 161 (see page 10 column 1 of

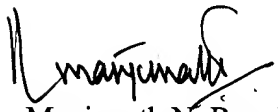
the published application). Among the different positions claimed in the instant application and in the reference application the amino acid that is being substituted are identical to one another. The portion of the specification (and the claims) in the reference application that supports the recited amino acid positions includes the embodiments (substitutions with a basic amino acid) that would anticipate the positions claimed in claims 1, 2, 4-6 herein. Claims of the instant application listed above cannot be considered patentably distinct over claims of the reference application when there is specifically recited embodiment that would anticipate mainly claims 1-2, 4-6 of the instant application. Alternatively, claims 1-2, 4-6 cannot be considered patentably distinct over claims of the reference application when there is specifically disclosed embodiment in the reference application that supports claims of that application and falls within the scope of claims 1-2, 4-6 herein because it would have been obvious to one having ordinary skill in the art to modify claims 1-2, 5-6 of the reference application by selecting the specifically disclosed embodiment that supports those claims i.e., a variant comprising a substitution at one or more positions of 144 and 161 wherein said substitution comprise a basic amino acid. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1, 2, 5-6 of the reference application.

In response to the above rejection, applicants maintain that application 10/307441 has been abandoned and a divisional application has been filed. Examiner has now rejected the claims against the divisional application 11/377644. Applicants also submit that they will file a terminal disclaimer when there is an indication of allowable subject matter. Examiner has retained the above rejection for reasons of record.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

December 12, 2006

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4-7,9,11-14,16,18,20-23,25,27,29-32,34,37-41,43,44,46,48,49 and 56-71.